UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,171	10/17/2003	Craig Bonsignore	CRD-5056	9527

27777 7590 07/12/2007

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/688,171	BONSIGNORE, CRAIG	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

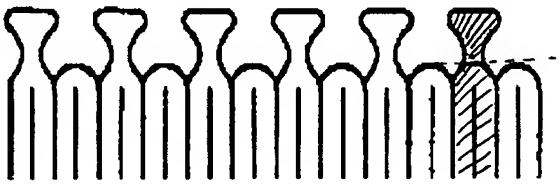
Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/19/2007 have been fully considered but they are not persuasive. Applicant has added the limitation of hour-glass shaped bridging elements with substantially flat ends. It appears that this limitation is drawn to the embodiments shown in fig. 22-24. However, the bridging elements (such as 2212) do not appear to be hour-glass shape sections extending from the apeces of the plurality of loops because the end of the bridging element that connects to the apex of a loop does not appear to have an enlarged area. Since this shape does not appear to be hour-glass in fig. 22-24 and the bridging elements are not disclosed as "hour-glass" in the instant specification, the limitation of an hour-glass bridging element is being considered new matter. As seen below, the apex line for a loop with a bridging element connected to it has been drawn in. The bridging elements can only be considered hour-glass shaped if they include a portion of the loop and therefore they would no longer be extending from the apex of the loop.



2. Since this shape is being considered substantially hour-glass, the bridging elements disclosed by Stenzel (U.S. 6,540,777) and Blank (WO 03/075797) are being considered substantially hour-glass shaped with substantially flat ends. "Substantially hour-glass shape" will be treated as requiring half of an hour-glass shape. The limitation of the hour-glass shape sections of two adjacent bridging elements on the same stent segment forming a locking

mechanism for a bridging element on an adjacent tubular stent segment does not necessitate that the two bridging elements together form a locking mechanism for the same bridging element on an adjacent tubular stent segment. It is also noted that this bridging element on an adjacent tubular stent segment does not have to be hour-glass shape.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the bridging elements in fig. 22-24 are not disclosed in the specification as being hour-glass shaped.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim includes the limitation of "one or more bridging elements comprising hour-glass shape sections and substantially flat ends, the one or more bridging elements extending from the apeces of the plurality of loops...". However, as discussed in more detail above, the bridging elements do not appear to be hour-glass since start at the apex of a loop.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 includes the limitation of "one or more bridging elements extending from one or more apeces of the plurality of loops" which form an interlocking mechanism with a bridging element on an adjacent tubular stent segment. It appears to the examiner that the limitation should read "two or more bridging elements" since the claim later includes the limitation that two adjacent bridging elements on the same tubular stent segment form a locking mechanism...."

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 10 and 11** are rejected under 35 U.S.C. 102(e) as being anticipated by Stenzel (U.S. 6,540,777). Stenzel discloses an intraluminal medical device having an unexpanded

configuration and an expanded configuration comprising one or more tubular stent segments, each tubular stent segment including a plurality of longitudinal struts being connected on opposite ends by the loop to form a substantially S-shape configuration, and one or more bridging elements extending from one or more of an apex of the plurality of loops. The bridging elements are substantially hour-glass shaped (see above regarding the interpretation of hour-glass based on fig. 22-24 of the instant specification) with substantially flat ends (see fig. 3) and extend from the apeces of the plurality loops on adjacent tubular stent segments (see fig. 1 which shows placement of bridging elements). Two adjacent bridging elements on the same tubular element form a locking mechanism for a bridging element on an adjacent tubular segment. It is noted that the language of the claim does not necessitate that the two adjacent bridging elements form a locking mechanism for the same bridging element on an adjacent tubular segment. The stent may be made of nitinol (col. 9, ll. 63).

8. **Claims 10 and 11** are rejected under 35 U.S.C. 102(e) as being anticipated by Blank (WO 03/075797). Blank discloses an intraluminal medical device having an unexpanded configuration and an expanded configuration comprising one or more tubular stent segments, each tubular stent segment including a plurality of longitudinal struts being connected on opposite ends by the loop to form a substantially S-shape configuration, and one or more bridging elements extending from one or more of an apex of the plurality of loops. The bridging elements are substantially hour-glass shaped (see above) with substantially flat ends (see fig. 2) and extend from the apeces of the plurality loops on adjacent tubular stent segments. Two adjacent bridging elements on the same tubular element form a locking mechanism for a bridging element on an adjacent tubular segment. It is noted that the language of the claim does not necessitate that the two adjacent bridging elements form a locking mechanism for the same

bridging element on an adjacent tubular segment. The stent may be made of nitinol (col. 9, ll. 63).

9. The stent may be made of nitinol (see page 1).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. **Claims 12-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stenzel or Blank in view of Davila et al. (U.S. 6,863,685). Stenzel disclose the invention substantially as described above, further disclosing that the medical device is made of nitinol (col. 9 ll. 63 of Stenzel; page 1 of Blank). Stenzel and Blank both fail to expressly disclose the amount of nickel and the amount of titanium present in the nickel-titanium alloy.

12. However, Davila et al. discloses that it is old and well known in the art to make a stent from a superelastic alloy of Nitinol. Davila et al. further discloses that it is old and well known in the art to construct a self-expandable stent from an alloy comprising about fifty to about sixty percent Nickel and the remainder titanium. Davila et al. states that the superelastic design of the stent makes it crush recoverable which makes it useful as a stent or frame for any number of vascular devices in different applications (col. 6 lines 32-45). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Stenzel or Blank to include the improvements disclosed by Davila et al. in order to gain the advantages of a medical device that is crush recoverable.

13. Regarding claims 13 and 14, Stenzel and Blank fail to disclose the addition of one or more radiopaque markers.

14. However, Davila et al. discloses that it is old and well known in the art to use radiopaque markers in a stent medical device. Davila et al. further discloses that radiopaque markers ensure proper positioning of the device within a lumen (col. 5, lines 9-11). Also, Davila et al. states that the markers may be positioned at other locations on the stent (col. 12 lines 52-53) and markers may be utilized to determine when and if a stent is fully deployed (col. 10, lines 64-65). Therefore, it would have been obvious to one of ordinary skill in the art to modify Stenzel or Blank to include the improvements made obvious by Davila et al. in order to gain the advantage of being able to ensure proper positioning of the device within a lumen. Positioning the markers into the mating protrusion would have been obvious to one of ordinary skill in order to determine when and if each segment of the stent is fully deployed.

15. **Claims 10, 11, 13, and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (U.S. 5,514,154) in view of Chew (U.S. 2003/0135266) and Thompson et al. (U.S. 6,814,746). Lau discloses an intraluminal medical device having an unexpanded and an expanded configuration comprising multiple tubular stent segments, each tubular stent segment including a plurality of longitudinal struts, and a plurality of loops connecting adjacent struts, the struts being connected opposite ends by the loops to form a substantially S-shape configuration. Lau fails to disclose one or more bridging elements extending from one or more apeces of the loops, the bridging elements comprising substantially hour-glass shape sections and substantially flat ends to create a locking mechanism for a bridging element on an adjacent tubular stent segment.

16. However, Chew teaches adding bridging elements and receptacles on the ends of stent segments so that individual stent segments can be connected or detached depending on how

long of a stent is desired (see summary of invention; fig. 5b). Chew suggests using a male and female type connection wherein the connection includes bridging elements extending from apeces of loops. Thompson discloses a female/male locking mechanism that includes substantially hour-glass shape sections and substantially flat sections (see 227; fig. 6) of an interlocking structure fitting with a bridging element on an adjacent stent. This locking mechanism is used to removably attach a stent to an interlocking structure on a delivery device. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Lau to include one or more bridging elements extending from one or more apeces of the loops, the bridging elements comprising substantially hour-glass shape sections and substantially flat ends, the bridging elements extending from the apeces of the loops on adjacent stent segments such that the hour-glass shape sections of two adjacent bridging elements on the same tubular stent segment form a locking mechanism for a bridging element on an adjacent tubular stent as made obvious by the teachings of Chew and Thompson in order to be able to adjust the length of the stent.

17. Regarding 11, the stent may be nitinol (see col. 6, ll. 61-64).

18. Regarding claims 13 and 14, Thompson teaches that it is old and well known to include radiopaque markers incorporated into bridging elements. (see fig. 6 and claim 9) and it would have been obvious to one skilled in the art to employ such radiopaque markers in the modified device of Lau in order to add in positioning each stent segment.

19. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau in view of Chew and Thompson as applied to claim 11 and further in view of Davila et al. (U.S. 6,863,685). Modified Lau discloses the invention substantially as described above, further disclosing that the medical device is made of nitinol. Modified Lau fails to expressly disclose the amount of nickel and the amount of titanium present in the nickel-titanium alloy.

20. However, Davila et al. discloses that it is old and well known in the art to make a stent from a superelastic alloy of Nitinol. Davila et al. further discloses that it is old and well known in the art to construct a self-expandable stent from an alloy comprising about fifty to about sixty percent Nickel and the remainder titanium. Davila et al. states that the superelastic design of the stent makes it crush recoverable which makes it useful as a stent or frame for any number of vascular devices in different applications (col. 6 lines 32-45). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Lau to include the improvements disclosed by Davila et al. in order to gain the advantages of a medical device that is crush recoverable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 6/26/2007

GLENN K. DAWSON
PRIMARY EXAMINER